JUN 11 2010

K093118

510 (k) Summary of Safety and Effectiveness for BrainLAB ACL

Manufacturer:

Address: BrainLAB AG
Kapellenstrasse 12
85622 Feldkirchen
Germany
Phone: +49 89 99 15 68 0
Fax: +49 89 99 15 68 33

Contact Person: Mr. Alexander Schwiersch

Summary Date: May 21, 2010

Device Name:

Trade name: BrainLAB ACL

Common/Classification Name: BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

Predicate Device:
VectorVision® ACL (K042512)
BrainLAB Knee (K073615)

Device Classification Name: Instrument, Stereotaxic
Regulatory Class: Class II

Intended Use:

Indications For Use:

BrainLAB ACL is intended to be used as an intraoperative image-guided navigation system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system, to a virtual computer image space on the model of a bone, overlaid with individually acquired patient landmarks.
The system is indicated for any surgical anterior cruciate ligament procedure in which the use of stereotactic surgery for the planning and navigation of interosseous canals may be appropriate, and where a reference to a rigid anatomical structure can be established.

Device Description:

ACL is an image guided surgery system for the replacement of torn ligaments in the knee joint. It is based on intra-operatively acquired landmarks that are used for planning and navigation. It supports the surgeon in the planning and drilling of transplants canals in the [redacted]position to regain the stability of the knee joint.

Substantial equivalence:

BrainLAB ACL has been verified and validated according to BrainLAB's procedures for product design and development.

To conclude the substantial equivalence, the following verification aspects were performed:

- Design review meetings
- Evaluation at special sites
- Tracking of software versions
- Subsystem & System Verification using Xtool
- Non-Xtool tests
- License group tests
- Installer tests
- Startup tests

To conclude the substantial equivalence, the following validation aspects were performed:

- Testing and evaluation under real world conditions
- Design reviews
- Software validation
- Literature research
- Literature evaluation
- Comparison with a previously marketed medical device
- Indications for use/Changed indications for use
- Non-clinical validation
- Preclinical and clinical validation
- Side effects

The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with the predicate device VectorVision® ACL (K042512) and BrainLAB Knee (K073615)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

BrainLAB AG
% Mr. Stefan Wimmer
Kapellenstrasse 12
85622 Feldkirchen
Germany

JUN 11 2010

Re: K093118
Trade/Device Name: BrainLAB ACL
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 04, 2010
Received: June 09, 2010

Dear Mr. Wimmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

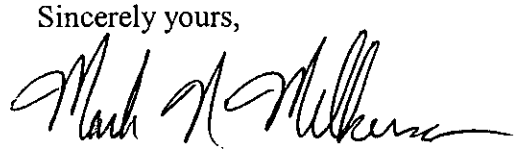
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093118

Device Name: ACL

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Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093118